2026 Predictions:
How AI and Regulation Will Reshape Biopharma Execution

Biopharmas have been advancing in how they connect data and processes across clinical, regulatory, safety and quality. In 2026, the operational focus will shift to creating even greater flow, connected execution across teams, supported by a technology backbone that improves data transparency, traceability and inspection readiness as Europe's regulatory expectations keep evolving. In parallel, AI will move from early capability augmentation to more generic AI that operates embedded in systems with compliance.

Below are five predictions for where life sciences are headed in 2026 that operate within clear guardrails.

Europe's Regulatory Landscape Will Push Teams Toward Inspection-ready Execution by Design

In 2026, regulatory change in Europe will feel less like a series of one-off milestones and more like a steady operating reality. Clinical teams will be firmly in a CTIS-first world under the EU Clinical Trials Regulation, which continues to raise expectations for consistency across countries, faster coordination and complete, traceable documentation, alongside broader moves toward more structured submissions such as eCTD 4.0. As organisations settle into this mode, the pressure shifts from "getting it done" to "getting it right, every time" with fewer exceptions and less tolerance for local workarounds.

At the same time, ICH E6(R3) continues to move the industry toward a more explicit, risk-based approach to GCP. Sponsors will increasingly be expected to demonstrate how quality is designed into a study and how oversight is executed across partners, data sources and systems. That narrows the gap between operations and compliance. It also changes what "inspection readiness" means day to day. It is not a scramble at the end. It is a continuous state that depends on clear process ownership, consistent documentation and a reliable trail of decisions.

Finally, structured data requirements will keep advancing. IDMP is one important signal of where regulators are heading, toward standardised product and substance data that can be reused and reconciled across the lifecycle. In practice, 2026 will reward companies that reduce manual handoffs between clinical, regulatory, safety, and quality and instead run on shared data and common process standards. That is how teams increase speed while staying audit-ready.

AI-readiness Will be Key as the Industry Builds Toward Agentic AI

In 2026, many companies will have moved past the novelty phase of AI. Early initiatives have shown varied success in targeted areas, such as summarisation, classification, extraction and draft generation. They also surfaced a consistent limitation: AI is only as dependable as the data, processes and governance underneath it. As expectations rise, especially with the EU AI Act shaping how regulated industries think about responsible AI, sponsors will increasingly treat AI-readiness as an operational capability, not a collection of pilots.

This is where the conversation shifts from "Can AI help?" to "Can AI help in a way we can trust, explain and scale?" The path to that outcome is not mysterious, but it is demanding:

- Harmonised data and metadata so AI outputs are grounded and consistent
- Standardised workflows so tasks can be executed with clear control points
- Strong governance so responsibility, validation and monitoring are explicit
- Audit-friendly traceability so decisions can be understood and defended

These foundations are also what make the next phase possible, agentic AI. In 2026, more organisations will begin operationalising controlled, task-based agents that can initiate workflows, check completeness, summarise outcomes, flag exceptions and route work to the right people. The winners will be the companies that pair AI with disciplined processes and connected data, so agents improve cycle time and quality without introducing unacceptable risk.

New EMA–FDA Principles Will Further Shape Biopharma's AI Operating Model

That shift toward AI-readiness is now being reinforced by regulators, not just through European policy signals, but through growing alignment on what "good" looks like when sponsors use AI across the drug development lifecycle. In January, the EMA and FDA published joint guiding principles for good AI practice in drug development, marking a turning point toward a more disciplined, operational approach to AI in biopharma.

For sponsors, the value of the principles is that they establish a shared reference point for what will matter as AI moves from pilots into regulated workflows. They do not prescribe specific technologies. Instead, they emphasise how AI should be designed, assessed, deployed and managed over time, including a clearly defined context of use, strong data governance and documentation, lifecycle controls, and clear, essential information to support oversight.

In practice, this raises the bar for any AI used in GxP-relevant activities. If AI supports protocol development, safety signal triage, document classification or quality decision-making, sponsors need to be able to support oversight with credible evidence. That includes tracing inputs back to authoritative sources, understanding how a model is trained or configured for its intended context of use, and showing where human responsibility sits for decisions, including when outputs are reviewed, overridden or escalated.

These expectations have real architectural consequences. Fragmented point solutions make end-to-end assurance harder to demonstrate across clinical, regulatory, safety and quality, especially as systems and processes evolve. Data provenance can be lost in handoffs and local workarounds, and documentation becomes difficult to keep consistent and verifiable over time, precisely where regulators are signalling the need for stronger lifecycle management and defensible records.

An industry cloud with a shared data foundation makes these expectations more achievable. When data is harmonised, workflows are standardised and governance is built in, sponsors can better contextualise, audit and trust AI-supported outputs without turning every question into an investigation. In that sense, regulatory alignment around AI reinforces the industry's broader move toward connected execution. AI reliability depends on data quality and provenance, and both depend on coherent operational design.

Over the course of the year, many biopharmas will use the EMA–FDA principles as a blueprint, not to deploy AI everywhere, but to deploy it where guardrails are explicit, performance can be monitored and outputs can withstand regulatory scrutiny. Regulation is not constraining innovation. It is clarifying the conditions under which innovation can scale responsibly.

Clinical Trial Data Flow Will Advance Recruitment and Improve Patient Access and Experience

The flow of clinical data between sites and sponsors will yield faster, more efficient trials. Study information will go straight to physicians to connect their patients with relevant research. New embedded AI will connect trial data between sponsors and sites so that physicians can search for treatment and trial options based on a patient's conditions or test results. This direct-to-physician approach will reduce the industry's reliance on sites to find study participants to meet recruitment goals sooner and improve patients' access to clinical trials.

With less burden from patient recruitment requirements and modern technology, sites will see the promise of eliminating paper and manual source data verification (SDV) for clinical research associates (CRAs) become a reality. eSource tools will better connect upstream and downstream clinical data sources, first with EHRs, so that patient health data can merge more efficiently with trial data. When connected with EDC, source forms will be defined by a trial definition, so data can flow faster and with more clarity to the sponsor. This data flow will streamline study visits for patients and advance trials for sites and sponsors.

Agentic AI Lab Assistants Will Drive Connectivity and Speed

Labs will move beyond chatbots to embed agentic lab assistants that connect highly specific tasks in a regulated environment. QC labs are turning their attention to the efficiency potential of AI agents and steering effort toward activating them across people and processes. However, the technology ecosystems in QC labs are fragmented and paper-based processes persist. Companies will modernise and consolidate systems, standardise data and workflows, and integrate quality assurance to reap the productivity gains of QC-specific AI.

Lab analysts will work alongside agents capable of starting workflows, summarising outcomes, and observing and analysing trends. This will advance proactive risk management by identifying issues early on and driving right-first-time execution. The outcome will be a highly effective and efficient QC lab where people and agents work together to shorten batch cycle times.

What These Shifts Mean for 2026

Across these predictions, there is convergence toward execution. Regulatory expectations for transparency, traceability and consistent oversight are increasing. At the same time, AI is driving a deeper look into operational foundations, because agents cannot scale on fragmented data and inconsistent processes. In 2026, the organisations that move the fastest will be the ones that can automate data flow across clinical, regulatory, safety, and quality with an inspection-ready development foundation and apply AI in effective ways that teams can trust. They will shift investment from isolated pilots to repeatable operating models, shared data standards, standardised workflows and governance that makes accountability explicit. They will simplify system landscapes so AI can work end-to-end, not inside silos, and so performance can be monitored and improved over time. The outcome is practical and measurable: fewer handoffs, fewer surprises, stronger compliance and faster delivery of therapies for patients.

Rik Van Mol

Rik Van Mol leads R&D and Quality strategy in Europe and is responsible for overall growth and execution of the European market.